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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,694

09/11/2006

Michel Quoniam

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EXAMINER

CHU, KING M

ART UNIT

PAPER NUMBER

3728

NOTIFICATION DATE

DELIVERY MODE

05/20/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/585,694	Applicant(s) QUONIAM, MICHEL	
	Examiner KING M. CHU	Art Unit 3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 March 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings were received on 03/09/2010. The Examiner permitted the entry of these drawings only to the extent that it shows a generic inhaler. None of its structural limitations, features, and any reference to the details of the inhaler will not be entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4, 7-9, 11, 13, 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekelius et al. (6,637,431) in view of Razeti (2003/0108714).

In reference to Claim 1

Ekelius discloses a blister strip (12) for use in a fluid or powder inhaler, and including a plurality of blisters (13), each formed by a reservoir (created by 19) including an opening (at the top of 19, see Figure 10) that is sealed in leaktight manner by a tearable layer (20) and a cavity layer (18) that is provided with cavities (19) forming the blister walls.

Ekelius discloses the claimed invention as discussed above with the exception of the following claimed limitations that are taught by Razeti: a base layer (19) that is provided with openings (23, Figure 5) forming the openings of the blisters, and said tearable layer (20, of Ekelius see above) comprising a first tearable-layer portion (21) that

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is disposed between said base layer (19) and said cavity layer (18 of Ekelius), and a second tearable-layer portion (22) that is disposed on the opposite side of said base layer, said first and second tearable-layer portions being connected together at each opening of the base portion (see figures 4 and 5, where the first and second tearable layers (21 and 22 are connected at 23 and 24).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti so that the tearable layer in Ekelius is modified with features of Ekelius, in order to make the container opening operations convenient for users, as taught by Razeti (column 1, paragraphs 0011).

In reference to Claim 2

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 1 and Razeti further teaches that the first and second tearable-layer portions are made from the same material (21, col. 3 paragraph 0028, and 22, col. 3, paragraph 0035, are made from polythene).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti for reasons stated in claim 1.

In reference to Claim 3

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 1 and Razeti further teaches that the first and second tearable-layer portions are connected together as a single part in each opening of the base layer (see Figure 5, where 21 and 22 are connected as a single part).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti for reasons stated in claim 1.

In reference to Claim 4

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 3 and Razeti further teaches that the single-part connection is made by fusing material (21 and 22 are fused together since 22 is a hot-extruded polythene which fuses to 21).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti for reasons stated in claim 3.

In reference to Claim 7

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 1 with the exception of the following claimed limitations: the first and second tearable-layer portions comprises a film having thickness that is less than 100 μm , advantageously lying in the range 10 μm to 40 μm , and preferably equal to 30 μm .

However Razeti discloses that the second tearable layer 22 is between 12 and 15 microns, and 21 is 30-40 microns. see col. 3, paragraph 0033-0037). Furthermore it has been held that the thickness of the tearable layers of a claim were disclosed in the prior art (Razeti), it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In reference to Claim 8

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Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 1 and Razeti further teaches that the base layer (19) comprises polyester (col. 3, paragraph 0028)

In reference to Claim 9

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 1 with the exception of the following claimed limitations: the base layer comprises a film having thickness that is less than 100 μm , advantageously lying in the range 40 μm to 60 μm , and preferably equal to 50 μm .

However Razeti discloses that the base layer (19) is 12 microns. see col. 3, paragraph 0033).

Furthermore it has been held that the thickness of the base layer of a claim were disclosed in the prior art (Razeti), it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In reference to Claim 11

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 1 and Razeti further teaches: the tearable layer further includes a first aluminum layer (12) that is fastened (via 14 and 15) to said second tearable layer portion (22).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti to that an aluminum layer is fastened to the second tearable layer portion in order to provide an assured barrier against contaminations of the product, as taught by Razeti (col. 1 paragraph 0012).

In reference to Claim 13

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 13 and Razeti further discloses that a polyester layer (15) and an adhesive layer (14) are disposed between said second tearable-layer portion and said first aluminum layer (see Figures 4 and 5).

In reference to Claim 20

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 1 and Ekelius further teaches a dry-powder inhaler (1 and 4, see Figure 3) comprising the blister strip according to claim 1 (see Rejection of claim 1).

In reference to Claim 21

Ekelius discloses a blister strip (12) for use in a fluid or powder inhaler, comprising: a blister (13) formed by a reservoir (created by 19) comprising a blister opening (at the top of 19, see Figure 10); a first tearable layer (20) sealing the blister opening (see Figure 10).

Ekelius teaches the claimed invention as discussed above with the exception of the following claimed limitations that are taught by Razeti: a base layer (19) above the first tearable layer (the first tearable layer 20 of Ekelius is replaced with 21 of Razeti) and comprising a base layer opening (23) corresponding to the blister opening (container opening 24); a second tearable layer (22) above the base layer and connected to the first tearable by a material connection (see Figure 5, 21 and 22) passing through the base layer opening so that, upon lifting the second tearable layer (22), an edge of the base layer opening tears the material connection formed between the first tearable layer and the

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second tearable layer (see figure 5 where lifting 22 tears the material connection formed at the opening), thereby unsealing the blister opening (see Figure 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti so that the tearable layer in Ekelius is modified with features of Ekelius, in order to make the container opening operations convenient for users, as taught by Razeti (column 1, paragraphs 0011).

In reference to Claim 22

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 21 and Razeti further teaches that the first tearable layer and the second tearable layer form an integral one-piece construction (see Figure 5 where 21 and 22 form an integral one-piece construction).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti for reasons stated in claim 21.

4. Claim 1 rejected under 35 U.S.C. 103(a) as being unpatentable over Ekelius et al. (6,637,431) in view of Razeti (2003/0108714) and further in view of Fuller et al. (Fuller 2002/0008046).

In reference to Claim 5

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 1 with the exception of the following claimed limitations that are taught by Fuller: the tearable layer comprises polyethylene (Fuller teaches that polyethylene was a common material used in known blister packs, col. 3, paragraph 0023-0024).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti and Fuller in order to provide a strong material for enclosing medication or pills, as taught by Fuller (col. 1, paragraph 0002).

In reference to Claim 6

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 1, that the said first and second tearable-layer portions are constituted by a continuous film (since 22 is joined to 21, 21 and 22 are considered to be a continuous film), with the exception of the following claimed limitations that are taught by Fuller: the tearable layer is polyethylene (Fuller teaches that polyethylene was a common material used in known blister packs, col. 3, paragraph 0023-0024).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti and Fuller in order to provide a strong material for enclosing medication or pills, as taught by Fuller (col. 1, paragraph 0002).

In reference to Claim 10

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 1 with the exception of the following claimed limitations that are taught by Fuller: the cavity layer comprises polyethylene and/or polypropylene (Fuller teaches that polyethylene and polypropylene were a common material used in known blister packs, col. 3, paragraph 0023-0024).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti and Fuller in order to provide a strong material for enclosing medication or pills, as taught by Fuller (col. 1, paragraph 0002).

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In reference to Claim 12

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 11 with the exception of the following claimed limitations: the first aluminum layer has thickness that is less than 50 μm , advantageously lying in the range 10 μm to 30 μm , and preferably equal to 20 μm .

Fuller teaches an aluminum foil that had a thickness of 0.0008 inch which is approximately equal to 20.32 microns (see col 3, paragraph 0025).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti and Fuller in order to provide a strong material for enclosing medication or pills, as taught by Fuller (col. 1, paragraph 0002).

In reference to Claim 15

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 1 with the exception of the following claimed limitations that are taught by Fuller: the cavity layer further includes a second aluminum layer (Fuller teaches that it was well known in the art at the time of the invention to use an aluminum foil to be attached to the blister sheet to provide strength as well as provide a backing layer, col. 1 paragraph 0004).

In reference to Claim 16

Ekelius in view of Razeti and Fuller discloses the claimed invention as discussed above for claim 15 with the exception of the following claimed limitations: a polyester layer and an adhesive layer are disposed between said cavity layer and said second aluminum layer.

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However Razeti does teach a polyester layer (15) and an adhesive layer (14) disposed between an aluminum layer (12) and another layer (22).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti and Fuller to provide the same layering to the cavity layer in order to assure barrier against contaminations of the product contained in the container, as taught by Razeti (col. 1, paragraph 0012).

In reference to Claim 18

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 1 and Razeti further teaches the a strength of the adherence of the tearable layer to the base layer between the openings is different from a strength of the adherence in the proximity of said openings (see Figures 4 and 5 where layers 21 is not adhered to the base layer 19 at the proximity of the opening, therefore the strength of the adherence is different and in Figure 5 the strength of the tearable layer 21 and 22 is adhered stronger to each other than to the proximity of the opening 24 and 23).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti for reasons stated in claim 1.

In reference to Claim 19

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 1 and Ekelius further teaches that the blisters contain a pharmaceutical powder (Abstract).

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5. Claim 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Ekelius et al. (6,637,431) in view of Razeti (2003/0108714) and further in view of Lippert (4,938,414).

In reference to Claim 14

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 1 with the exception of the following claimed limitations that are taught by Lippert: the tearable layer includes a first outer layer, preferably formed by a printer's varnish (Lippert teaches that a printer's varnish maybe applied to the face of sheets, where the printer's varnish in itself is a layer).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti and Lippert in order to provide an advertisement, as taught by Lippert (col. 3, lines 24-26).

In reference to Claim 17

Ekelius in view of Razeti discloses the claimed invention as discussed above for claim 1 with the exception of the following claimed limitations: the cavity layer includes a second outer layer, preferably formed by a protective layer or by a layer of varnish (Lippert teaches that a printer's varnish maybe applied to the face of sheets, where the printer's varnish in itself is a layer).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti and Lippert in order to provide advertisement, as taught by Lippert (col. 3, lines 24-26).

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Ekelius in view of Razeti in view of Lippert discloses the claimed invention as discussed above and Razeti teaches that adhesive layers are used to adhere two layers together (see Figures 4 and 5, adhesive layer 14).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ekelius in view of Razeti and Lippert for reasons stated in claim 1.

Response to Arguments

6. Applicant's arguments, filed 03/09/2010, with respect to claim 1 have been fully considered and are not persuasive.

In reference to Claims 1-4, 7-9, 11, 13 and 20-22

7. In response to applicant's argument that Razeti (US 2003/0108714) is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the sealing layer of Razeti can be applied to seal a receptacle (i.e. the receptacle of Ekelius). Both references are in the art of retaining and dispensing ingestible articles and there is a logical combination between the two cited references.

8. Applicant further argues that the neither Ekelius nor Razeti teach a guaranteed dispensing of the entire dose and to allow breath-actuation. The Ekelius reference teaches an inhaler that is capable of dispensing an entire dose of medication (i.e. a user can inhale the contents within the blister, col. 1, ll. 29-38).

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9. Applicant further argues that Razeti's containers are individual and they are intended to be manually opened. The Razeti reference is cited to show the sealing layer feature, which can be combined with the Ekelius reference so that the sealing layer of Ekelius is replaced with the sealing layer of Razeti. When the inhaler of Ekelius is in use, the modified Ekelius in view of Razeti would still perform the task of dispensing a dose of medication. In as much as the applicant has claimed the inhaler in combination with the blister strips, the prior shows the claimed limitations of applicant's invention.

10. Applicant argues that elements 21 and 22 are clearly two pieces bonded together thus cannot be a one-piece construction. In as much as the applicant has claimed the one-piece construction, element 21 and 22 do form a one-piece construction when they are bonded together.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to KING M. CHU whose telephone number is (571)270-7428. The examiner can normally be reached on Monday - Friday 8AM - 5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ehud Gartenberg can be reached on (517)272-4828. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KING M CHU/
Examiner, Art Unit 3728

/Ehud Gartenberg/
Supervisory Patent Examiner, Art Unit 3728